Brian McCarthy PhD
"Renvyle", Wilton Avenue, Cork, Ireland
Tel. +353-21-543180 Fax +353-21-312555

FACSIMILE **TRANSMITTAL**

FAX - 001 (301) 594-1807 **January 18, 1998**

ATTN: George A. Mitchell (HFV-6)
CVM, MPN2 - Room 484

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Re: "Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses"- Discussion Draft of 19 December 1997.

George,

Attached find Discussion Draft contribution and comments, as suggested!

I appreciate the opportunity to contribute to the discussion on drug availability for aquaculture disease control and/or treatment and Food Safety assurance considerations.

I look forward to seeing of significant Minor Species Working Group contribution towards resolution of some the difficulties in the areas of concern.

Sincerely,

Brian McCarthy

Brian McCarthy, Ph.D.

Member of the American Society of Agricultural Consultants

IV. Proposals to increase the number of approved animal drugs for minor use

A. MODIFICATIONS OF EXTRALABEL PROVISIONS

The MOST practical means of treatment of aquaculture species is via the feed!

There is no basis, except omission, for the exclusion of aquaculture from the extralabel provisions of AMDUCA and resultant regulations.

Antibiotic resistance or environmental contamination in aquaculture may require more complex assessment than other species considered under AMDUCA.

While "Public bodies of water are strongly regulated by state and federal agencies", it is evident that ocean-based aquaculture production dilution may justify separate criteria of assessment than those for essential for inland or fresh-water production.

B. REMOVAL OF DISINCENTIVES

The Working Group are advised that:-

Enforcement policy, programs and effectiveness supportive of AMDUCA extra-label provisions are essential to the investment and development of drugs for minor species.

There ARE apparent short-falls in a coherent post-AMDUCA enforcement that negate elements of AMDUCA, frustrating veterinarians, confusing producers and serving to promote chemical substitutes as replacement for approved drug product use without regard for Food Safety, Human Safety and Environmental considerations.

In addition:-

Food Safety may require CONGRESSIONAL ACTION (Item 2), as "over-the-counter drugs" are not (currently) subject to AMDUCA extralabel provisions.

and,

When used to support a supplemental minor use NADA, an Approved Drug file should NOT be subject of further review *in the absence of detailed scientific or circumstantial support that would otherwise justify such action.*

C. ENHANCEMENT OF EXISTING PROGRAMS FOR DATA DEVELOPMENT

It is essential to stress that supplemental drug applications are a more rapid and cost-effective means of assuring available drugs for minor species, and minor use.

A Minor Use Database would not make a significant contribution to aid minor species drug development, as communication between parties and institutions, in different jurisdictions, is presently very effective.

It may be cost effective to consider an FDA "prognosis" to NRSP-7 (and others) on the probable Human Safety requirement considerations for a candidate substance.

Investment in research on the development of etiology data, as part of health assurance, could reduce the need for some minor use animal drugs.

D. INCENTIVES TO PURSUE MINOR USE DRUG APPROVALS

Extended Exclusivity must be weighed against costs and the absence of treatments.

Added exclusivity is recommended for Original NADAs to support supplemental drug approvals.

Appropriate exclusivity for New Claims, against generic approval, and enforcement are essential to investment in an original minor use NADA.

Investment in an Orphan drug model approach, for minor species drug availability, may be limited by Food Safety cost constraints.

Shorter review time-frames would greatly assist the filing of minor uses.

Food Safety is "Significant New Data" intrinsic to drugs for food animal species!

E. DATA SHARING BY MAJOR SPECIES NADA HOLDERS

Sharing of data is intrinsic to supplemental applications for minor species or minor use drugs, and this must be a primary focus for the Working Group.

An original sponsor's liability for "unknown consequences", consequential to a third-party supplemental application, in a minor species or minor use treatment is a matter between the principals involved.

A further exclusivity extension, to an Original Sponsor, would be a practical incentive.

F. CREATION BY STATUTE OF A "MINOR USE ANIMAL DRUG" PROGRAM

This would primarily benefit minor use drugs and create an increased awareness of minor (food) species use drugs.

It is difficult to reconcile a minor (food) species use drug benefit, under the proposed statute, as Food Safety and Residue depletion are major cost requirements.

G. CONDITIONAL DRUG APPROVAL FOR MINOR USES INVOLVING NON-FOOD ANIMALS

A conditional non-food animal approval proposal provides an incentive, provided that:-

a) The potential interim non-food animal marketing for the drug is substantial, and,
b) Both enforcement activity, and intermediary monitoring, are proactive!

H. ALTERNATIVE APPROVAL STANDARDS/EXPERT REVIEW PANELS FOR MINOR USES INVOLVING NON-FOOD ANIMALS

The proposal would benefit non-food animal treatment availability but, at the same time, stretch FDA monitoring and enforcement resources on food-animal exposure.

I. INTERNATIONAL HARMONIZATION

Food Safety dictates regulatory requirements cannot become a "minor versus major species" Consumer concern nor a Harmonization (veterinary drug) agreement issue.

Incorporating "minor species" (per se) in Harmonization discussions does not resolve short-termed approved drug availability.

Establishment programs to review foreign approvals, for FDA "minor species", should an ongoing internal function in support of International Harmonization discussions.

The processing of "minor species drugs" is an internal problem, as Harmonization agreements establish mutually agreed criteria and standards in veterinary drugs.

It might be well to reflect on how countries exercise their "individuality" in considering current US/FDA approval relevance in meeting their own drug approval requirements.